REMARKS

This Response is directed to the Office Action mailed October 23, 2002. Presently, all claims 1, 2, 4-6 and 10-16 stand rejected. Applicants respectfully request re-examination and reconsideration of the claim rejections in view of the remarks provided hereinbelow.

In the Office Action, the Examiner rejected claims 1, 2, 4, 10, 13 and 16 under 35 U.S.C. §103(a) as being unpatentable over Parker (USP 5,221,270) in view of Jansen (USP 6,152,912). According to the Examiner, Parker discloses all of the recited structure with the exception of using fluorinated ethylene propylene (FEP) as the polymeric material. The patent to Jansen is cited for teaching that FEP can be used as sleeves and catheters. According to the Examiner, it would have been obvious to modify the polymeric material of Parker to be made of any suitable plastic for use with catheters, including FEP.

Independent claim 1 of the present invention, as amended, is directed to an introducer sheath comprising a shaft extending from a proximal end portion to a distal end portion, and a distal tip section at the distal end portion of the shaft. The distal tip section comprises FEP containing between about 20% and 75% by weight of radiopaque material selected from tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead. The distal section is considerably more radiopaque than the proximal section.

FEP is known in the art as a desirable sheath material. FEP has a low coefficient of friction, and allows the passage of catheters and other interventional devices with a minimum of resistance. In addition, FEP has good flexibility and kink resistance in fairly thin walls, which are favorable features in an introducer sheath. Lightly loaded FEP has been used as sheath material for many years, and physicians are very comfortable with its feel and characteristics. Although radiopaque, highly loaded catheter tips have been known, highly loaded FEP sheath tips have not. FEP has been made radiopaque, but not nearly as x-ray opaque as the material in the claimed sheath. The high percentage load of radiopaque material in the present invention results in a material that can be as x-ray opaque as the metal band commonly used in such sheaths, thus eliminating the need for the band. Having a radiopaque distal FEP section enables the physician to determine the exact positioning of the sheath while inserted in the bodily

passage of the patient, since the radiopaque marking is exactly at the distal tip of the introducer sheath, rather than spaced slightly proximately from the tip when annular bands of a radiopaque material are utilized. Utilizing a radiopaque section rather than an annular band of a metallic alloy as the radiopaque marker also maintains the flexibility of the section, which assists in minimizing wall trauma when small bodily passages are navigated. Such flexibility can be adversely affected if a metallic band is utilized at or near the distal tip.

As stated in the present application, prior art tip members are commonly made of copolymers that are substantially loaded with radiopaque materials such as tungsten or barium. The tip member of Parker was made of a polyether block amide material, with nylon being a named example. Although the art teaches that high loadings of radiopaque material could be accomplished with copolymers and polyether block amides such as nylon, it was unexpected that high loadings of radiopaque material could be attained with FEP and still result in a stable extrudable composition that could be bonded to (at least) other FEP material. As stated in the present application, a loading of 20% tungsten results in a radiopacity that is roughly equivalent to that generated by a 40% loading of barium sulfate. Page 4, lines 21-25. FEP sheaths have contained about 5-40% barium sulfate filler, but are not known to be fillable to over 40% barium sulfate particles and still result in a stable extrudable composition. Page 4, lines 26-29.

Neither the Parker reference not the Jansen reference discloses a distal FEP sheath portion having high loadings of radiopaque markers. In fact, the Examiner noted in the Office Action that the Parker reference does not teach the use of FEP. Although Jansen does disclose the use of FEP, in that instance it is used as a lubricious inner liner material (Col. 9, lines 35-43) , or as a segment of lesser flexibility (**218** in Fig. 2F). This segment of lesser flexibility is then coupled with more flexible distal segments 212, 214, 216 of other compositions. Neither reference discusses the difficulty in attaining high loadings with FEP, nor the problem of increasing the radiopacity of certain segments relative to other segments. Thus, for the foregoing reasons, Applicants respectfully submit that claim 1 is not obvious in view of the cited combination.

Claims 2, 4, 10, 13 and 16 are dependent, directly or indirectly, on independent claim 1, and therefore include all of its limitations. Thus, Applicants respectfully submit that these claims are also not obvious over the cited Parker and Jansen combination for at least the same reasons that claim 1 is not obvious.

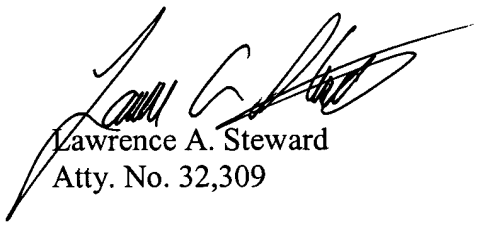
Claims 5, 6, 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Jansen for the reasons provided above, and further in view of Hopkins (USP 5,948,489). These claims are also dependent, directly or indirectly, from independent claim 1, and therefore include all of its limitations, including the limitation of a FEP distal tip section. Thus, for the reasons specified above, Applicants submit that these claims are also not obvious in view of the cited combination.

Claims 14 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parker '270 in view of Hopkins and Jansen. Independent claim 14 is narrower than claim 1, in that it is directed to an introducer sheath having an FEP distal tip section that contains between about 50% and 55% by weight of tungsten radiopaque particles that range in size between about 1.4 and 1.8 microns.

According to the present specification, it is believed that the high density of the tungsten particles, the small particle size and the narrow size distribution range may act to permit such high loading levels. The Parker and Jansen references were distinguished in the remarks provided above. Hopkins was cited as disclosing the use of radiopaque materials such as tungsten in a catheter, where it is known that the particles can be as small as 0.9 microns. As with the other references, however, Hopkins does not teach loading FEP tips with tungsten particles, nor does it indicate an awareness of the problems in loading such tips with radiopaque particles such as tungsten. Although Hopkins does speak of particle size in passing, there is no indication that particle size may affect high loadings such as described in the claim. In fact, it appears that Hopkins utilizes low loadings of tungsten, since notwithstanding the use of particles of the specified size, a radiopaque marker band **14** is still heat shrunk over the tip material. The present invention does not utilize, and in fact has no need for, a radiopaque marker band, since the high loadings of tungsten make the entire tip portion radiopaque.

Based upon the foregoing, Applicants respectfully submits that claims 1, 2, 4-6 and 10-16 are in condition for allowance. Accordingly, Applicants respectfully request the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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